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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/019,837	09/10/2002	Nikolaos S. Soukos	00786-421002	8657

7590 09/12/2005
Fish & Richardson
225 Franklin Street
Boston, MA 02110-2804

EXAMINER

CAMERON, ERMA C

ART UNIT PAPER NUMBER

1762

DATE MAILED: 09/12/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/019,837	Applicant(s) SOUKOS ET AL	
	Examiner Erma Cameron	Art Unit 1762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-27 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-27 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 10 September 2002 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|--|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date ____ | 6) <input type="checkbox"/> Other: ____ |

DETAILED ACTION

Claim Rejections - 35 USC § 112

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 1-18 and 22-27 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method in which the target material is coupled to the biofilm with a coupling medium, does not reasonably provide enablement for a method in which there is no coupling medium. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

See 8:21. This section of the specification says that the target material must be coupled to the biofilm by a coupling medium (emphasis added). The coupling medium, in other words, is a required aspect of the claimed invention.

3. Claims 1-4, 13-23 and 25-27 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method in which a target material is coupled to or disposed on the biofilm, does not reasonably provide enablement for a method that does not use

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a target material. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

See page 8. It appears that a target material is an essential aspect of the claimed invention.

4. Claims 1-27 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

a) Page 12, lines 7-16: 16 is referred to as both a “solution” and as a “target”.

Which is it?

b) 12:7-16: Laser pulse 20 is not shown in the figure.

c) 5:7: “capsular” has not been defined, and is therefore vague.

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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6. Claims 1-27 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

a) Claim 8-9: should be put into proper Markush terminology – selected from the group consisting of.

b) Claims 15: “capsular polysaccharide” has not been defined, either in the claim or the spec, and is therefore vague and indefinite.

c) Claim 22: it is not clear what “associated” means. Does it mean that the biofilm is attached to the surface, near the surface, a part of the surface??

d) Claims 1 and 24: claim 1 claims that the compound is delivered into the biofilm, whereas claim 24 claims that the agent passes through the biofilm. These appear to be different processes. Are both claims meant to claim the same process, or different processes?

e) Claim 19: it is not clear how the target material, reservoir and coupling medium relate to each other, spatially and process-wise.

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f) Claim 19: the use of the term “suitable” makes it unclear if the coupling medium actually mixes with the compound or not, or if the coupling medium is merely suitable for mixing with the compound.

g) Claim 12: “rapid” has not been defined and is therefore vague and indefinite.

Drawings

7. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they do not include the following reference sign(s) mentioned in the description:

- laser pulse 20 is not in Figure 1.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either “Replacement Sheet” or “New Sheet” pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all

obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. Claims 1-6, 8, 10, 12-18 and 22-27 are rejected under 35 U.S.C. 103(a) as being

unpatentable over Flotte et al, Proceedings of the SPIE, 2681, pp 160-166, 1996.

Flotte teaches laser-induced stress transients (compressive pressure waves) that aid molecules crossing cell membranes by increasing cell permeability. The laser is at 193 nm, up to 750 bars and a rise time of 10-15 nseconds, and uses polyimide as a target (see entire document), thereby meeting the limitations of claims 1-6, 8, 10, and 24-26. The wavelength, pressure, and rise time overlap with that claimed by applicant.

The subject matter as a whole would have been obvious to one having ordinary skill in the art at the time the invention was made to have selected the overlapping portion of the range disclosed by the reference because overlapping ranges have been held to be a prima facie case of obviousness. See *In re Malagari* 182 USPQ 549.

Cells would be inclusive of the bacterial cells of a biofilm, and a biofilm would be inclusive of a variety of bacteria, fungi, protozoa and polysaccharide, as well a site, as in claims 14-18 and 22-23. The molecules that are induced to cross the cell membrane would be inclusive of the antimicrobial agent of claim 12 or claim 27.

The rapid heating of claim 12 would be inherent to the process.

10. Claims 7, 9, 11 and 19-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Flotte et al, Proceedings of the SPIE, 2681, pp 160-166, 1996 taken in view of WO 98/23325.

Flotte is applied here for the reasons given above.

Flotte fails to teach all the details of claims 7, 9, 11 and 19-21.

'325 teaches using laser-induced impulse transients to deliver compounds, such as therapeutic agents (15:24-34), to epithelial cells (the broad band, compressive laser stress waves have a rise time of 1-200 ns, a peak pressure of 300-200 bars (see page 4)).

'325 further teaches that a coupling medium, which may contain a surfactant of sodium lauryl sulfate (5:3-16), a target material of metal such as aluminum or copper or polystyrene (3:8-18, 12:29-13:9), a transparent material bonded to the target material (3:8-18, 13:10-24) and a reservoir of the coupling medium and compound (3:19-28) are used as part of the apparatus for generating laser stress waves.

It would have been obvious to one of ordinary skill in the art to have incorporated the apparatus of '325 into the Flotte process because of the teaching of '325 that theirs is conventional apparatus for generating laser-induced stress waves.

Conclusion

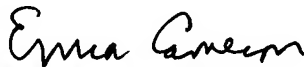
11. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

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12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Erma Cameron whose telephone number is 571-272-1416. The examiner can normally be reached on 8:30-6:00, alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Timothy Meeks can be reached on 571-272-1423. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



ERMA CAMERON
PRIMARY EXAMINER

August 26, 2005

Erma Cameron
Primary Examiner
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